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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/912,031 | 07/23/2001 | David Cook | Cerus-4900.10 | 4750 |

7590

04/22/2003

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/22/2003

05/02/03 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,031

Applicant(s)

COOK ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The response filed January 23, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-20 are pending and are examined on the merits.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Platz et al (U.S. Pat. 5,418,130).

Platz discloses processes wherein blood products, including red blood cells, are treated with quaternary ammonium or phosphonium-substituted halogenated psoralens to remove pathogens. See abstract. Note specifically that these compounds are cationic and, to the extent they can be derived from furocoumarin, can be considered "furocoumarin derivatives", as recited in claim 7. Note further Platz's preferred use of compounds containing ester moieties in the linker portion of the compounds (columns 10 and 11), thereby meeting the limitation requiring a frangible linker moiety. Platz further discloses that glutathione is suitable for use as a quencher to augment red cell defenses against free radical initiated damage. See col. 26, lines 41-44. The reference therefore discloses

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processes having all of the steps recited in the cited claims. Thus, Platz anticipates the cited claims.

All of applicant's argument on this issue has been fully considered but is not persuasive of error. Note specifically that, contrary to applicant's argument, Platz clearly discloses that psoralens act by binding covalently to DNA. See, e.g., column 28, line 21 through column 29, line 23; especially lines 23-26. ("Upon absorption of a UVA photon the psoralen excited state will react with a thymine or uracil double bond **and covalently attach to one nucleic acid helix.**") (Emphasis added.) Moreover, several of Platz's psoralen sensitizers are cationic. See, e.g., columns 32 and 33. Thus Platz clearly discloses contacting the claimed agent to the claimed sample.

Moreover, applicant has not demonstrated that the glutathione quencher disclosed by Platz fails to act as recited in the claims. Rather, because the prior art discloses contacting the claimed material with the claimed pathogen inactivating compound and the claimed quencher, the claimed result would appear to necessarily, i.e. inherently, occur. Because applicant fails to provide any demonstration as to why Platz fails to meet this limitation, despite performing the exact process steps recited in the claim, the rejection must be maintained.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al (U.S. Pat. 5,418,130).

As discussed above, Platz discloses a process wherein a pathogen-inactivating compound having the claimed structure, including frangible linker moiety, is quenched using glutathione. Platz does not disclose specific process parameters for the quenching process. However, the artisan of ordinary skill, seeking to practice Platz's inactivation process, clearly would have considered the determination of

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suitable and/or optimum process parameters, such as concentration of inactivating and quenching compounds, as well as duration of inactivation and quenching treatments, to have been a routine matter of optimization, and therefore obvious to the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore required.

All of applicant's argument has been fully considered but is not persuasive of error. As discussed above with respect to the § 102 rejection over Platz, Platz does in fact disclose the use of an electrophilic moiety which covalently binds to DNA. While the reason for contacting the claimed sample with the claimed compounds and claimed quencher may be slightly different than that disclosed by applicant, as applicant is surely aware, claimed subject matter must be held obvious if the prior art suggests its practice, even if the prior art motivation is different than applicant's. See, e.g., MPEP 2144, subsection entitled "RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE." Because the claimed result-effective process parameters would have been readily ascertainable by the artisan of ordinary skill through routine optimization, a holding of obviousness is required, absent some unexpected result coming from the use of the claimed process parameters.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-35 of U.S. Patent No. 6,093,725 ("Cook '725") in view of Platz et al (U.S. Pat. 5,418,130).

Claims 20-35 of Cook '725 recite inactivation of pathogens in materials, including the blood cell compositions recited in the instant claims, using the same compounds as recited in the instant claims. Claims 20-35 of Cook '725 differ from the instant claims in that they do not disclose a step of quenching the pathogen-inactivating reaction. However, as discussed above, Platz discloses that glutathione is suitable for use as a

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quencher to augment red cell defenses against free radical initiated damage. See col. 26, lines 41-44. Thus, the artisan of ordinary skill, recognizing the advantage of adding a quencher such as glutathione to protect the red cells from free radical damage caused by the pathogen inactivating compound of the patented claims, would have been motivated to have added a quenching compound to the pathogen inactivating process recited in claims 20-35 of Cook '725. Thus, because the instant claims do not patentably differ from the claims of Cook '725 when taken in view of Platz, a terminal disclaimer is clearly required.

As discussed immediately above, claims 1-20 are directed to an invention not patentably distinct from claims 20-35 of commonly assigned U.S. Pat. 6,093,725. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Pat. 6,093,725, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required

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under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

All of applicant's argument regarding the issue of obviousness-type double patenting has been fully considered but is not persuasive of error. While applicant asserts that the mechanism of action of the quencher in the claimed process is different than the mechanism of action in the Platz reference, applicant is again reminded that the prior art need only provide motivation for practicing the claimed subject matter, and that the motivation need not be the same as applicant's. See, discussion above; see also MPEP 2144, subsection entitled "RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE." Thus, while applicant asserts that the claims are not directed to a

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process which results in free radical damage, this assertion ignores the fact that the claims in fact encompass such a process. In short, applicant's argument ignores the breadth of both the claims and the prior art. The rejection must therefore be maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
April 14, 2003